A20

29. A protein hydrolysate as claimed in claim 20, which is soluble in water at a range of pH from 1 to 14.

All the changes are made for clarification and are based on the application and drawings as originally filed. It is respectfully submitted that no new matter is added.

REMARKS

The present amendment is in response to the Office Action mailed July 3, 2002, in which Claims 1-27 were rejected on the ground that certain languages in these claims render the claims indefinite and these claims are anticipated over prior art. Applicants have thoroughly reviewed the outstanding Office Action including the Examiner's remarks and the reference cited therein. The following remarks are believed to be fully responsive to the Office Action and, when coupled with the amendments made herein, are believed to render all claims at issue. Applicants respectfully request reconsideration and an early favorable action by the Examiner.

Specification has been amended to correct clerical errors. Claims 7-8, 10, 16-19, and 23-26 have been cancelled. Claims 1, 3-6, 9, 11-13, 20, 22 and 27 have been amended to correct grammatical errors and clearly point out what the invention is. Claims 28-29 are added. Claims 1-6, 9, 11-15, 20-22, and 27-29 are currently pending.

As to the Rejection under 35 U.S.C. §112, Second paragraph

Claims 1-27 stand rejected under 35 U.S.C. §112, second paragraph. The Examiner points out grammatical and typo errors. Also, the terms in the claims, for example "similar," "low," "decreased," "undesirable," "less hygroscopic," and "high

yield" are rejected as being indefinite. Cancellation of and amendments to the claims are made as the Examiner proposed.

Accordingly, the rejection under 35 U.S.C. § 112, second paragraph is not sustainable, and it is respectfully requested that the rejection be withdrawn in the light of the amendments.

As to the Rejection under 35 U.S.C. §102(b)

Claims 1-27 stand rejected under 35 U.S.C. §102(b) as being anticipated by Delrue et al. (U. S. Patent No. 5,100,679, "Delrue"). Applicants respectfully traverse this rejection as follow.

Delrue teaches a process of producing proteinous product from soy flour. This method comprises the steps of (1) pre-treating the pH-adjusted slurry with a viscosity-reducing agent to reduce viscosity; (2) heating the pretreated slurry to 85 °C or above to remove proteinaceous anti-nutritional factors; (3) hydrolysis using alpha-galactosidase and, optionally proteinases, at 35-60 °C, pH 4.0-55; and (4) drying of the resultant protein hydrolysate. The main purpose of Delrue is to reduce the viscosity of the slurry.

In contrast, the process of the present invention comprises the steps of (1) hydrolyzing the soy flour slurry using a proteolytic enzyme originated from plants at pH 5-9 and temperature of 53±5 °C for a range from 30 minutes to 6 hours; (2) inactivating the enzyme; (3) adjusting the pH of the slurry to a range between 6 and 7; and (4) separating insolubles and drying the resultant clarified liquor to obtain a protein hydrolysate.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each an every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as in contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226 (Fed. Cir. 1989).

According to the instant invention, an aqueous slurry of soy flour is subjected to hydrolysis without pretreatment using a viscosity-reducing agent and heating. By contrast, Delrue teaches hydrolyzing the soy flour slurry that is first treated with a viscosity reducing agent and heated. Accordingly, Delure does not teach or suggest that a soy flour slurry, which is not pretreated, be hydrolyzed.

In more detail, Delure teaches that the pretreated soy flour slurry at a temperature in the range of 85° to 150° C to inactivate the protein anti-nutritional factors. The heating treatment will remove the soybean whey component from the soy flour slurry, which is regarded as an undesirable component. (Delure, col. 5, ll. 54-56) Hence, the end product obtained by Delure process does not contain soybean whey component. By contrary, the end product of the instant process retains soybean whey components which occupy about one third of the total weight of defatted soybean materials.

Furthermore, Delrue does not teach to adjust the pH of the hydrolyzed slurry to a certain range, i.e., between 6 and 7 as stated in amended claim 1.

Accordingly, the rejection under 35 U.S.C. §102(b) is not sustainable and it is respectfully requested that the rejection be withdrawn in the light of foregoing discussion and amendments.

MARKED-UP CHANGES

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached paper is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully submit that all pending Claims 1-6, 9, 11-15, 20-22, and 27-29 as currently presented are in condition for allowance. If, for any reason, the Examiner disagrees, please call the undersigned attorney at 202-624-3947 in an effort to resolve any matter still outstanding *before* issuing another action. The undersigned attorney is confident that any issue which might remain can readily be worked out by telephone.

Favorable reconsideration is respectfully requested.

Respectfully submitted,

Dated: 12/23/02

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

The paragraph beginning on line 27 of page 1 is amended as follows:

United States Patent No. 5180597 claimed a process for hydrolyzed vegetable protein with enhanced flavor, which contains no detectable level of monochlorodihydroxypropanol[is described]. In the above reference, wheat gluten is hydroly[s]zed using Prozyme 6 (a fungal protease) at a temperature of 40-50°C, pH 6.5-7.0, enzyme concentration of 0.1-2% of substrate for a time period of 4h. The hydroly[s]zed protein is treated with gaseous HCl for deamidation before the addition of acid for inactivating the enzyme. The drawback in such hydrolysis is that [i6]it is likely to lead to racemisation of amino acids and the addition of acid increases the salt content in the product.

The paragraph beginning on line 4 of page 2 is amended as follows:

United Sates Patent No. 5077062 claimed a low sodium, low mono sodium glutamate soy dydrolysate that is prepared from soy material such as soy flour, soy [mean]meal or soy grits using fungal protease in water. The hydrolysis is conducted in the absence of acid or base at 90°C for 2 h. After deactivating the enzyme and de-watering the mixture, the resulting hydrolysate contains between 45 and 55 wt. % enzymatically hydrolysed soy based protein with an average molecular weight of 670,000 ± 50,000. The fungal protease used is different from the enzyme used in the present invention. The process is energy intensive due to the high temperature (90°C) used.

The paragraph beginning on line 13 of page 2 is amended as follows:

United States Patent No. 4757007 claimed a preparation of two hydrolyzed products using a protease from soy protein. The soy protein is hydroly[s]zed with papain or pepsin after precipitating with alcohol. The drawback of the process is that it involves the separation of the mixture of hydroly[s]zed products. Hydrolysis is carried out using

papain or pepsin. Acidification is carried out to bring down the pH to 2.5-5.0 to separate the two kinds of hydrolysates, which could lead to increase in salt content.

The paragraph beginning on line 20 of page 2 is amended as follows:

European Patent No. 0148600 B[]1 relates to the preparation of hydrolyzed protein from protein isolate after jet cooking or dynamic heating at 104°C for a few seconds and later cooled in a vacuum chamber before performing hydrolysis using bromelin. The protein was precipitated at its isoelectric point from an aqueous extract of the material before the hydrolysis. The drawback of the process is that the starting material protein isolate[, which] is more expensive. The process is a multi step process and energy intensive. The process further needs machines like the jet cooker and a vacuum chamber.

The paragraph beginning on line 24 of page 4 is amended as follows:

OBJECTS OF THE [Invention]INVENTION

The main object of the present invention is to provide a process for the preparation [for the preparation]of protein hydrolysate from soy flour from plant based protease.

The paragraph beginning on line 1 of page 6 is amendment as follows:

In one more embodiment of the present invention, they drying is effected by freeze drying, spray drying [and]or drum drying.

The paragraph beginning on line 10 of page 6 is amended as follows:

In another embodiment of the present invention, the protein hydrolysate has 2-2.2g/100ml bitterness recognition threshold units.

The paragraph beginning on line 30 of page 8 is amended as follows:

Trinitrobenzenesulphonic acid (TNBS) procedure[,] is an accurate, reproducible and generally applicable procedure for determining the degree of hydrolysis of food protein hydrolysates. The protein is dissolved/dispersed in hot 1% sodium dodecyl suplphate to a concentration of 0.25 - 2.5 x 10^{-3} aminoequivalents/L. A sample solution (0.25 ml) is mixed with 2 ml of 0.2125 M sodium phosphate buffer (pH 8.2) and 2 ml of 0.1% Trinitrobenzenesulphonic acid, followed by incubation in the dark for 60 min at 50 C. The reaction is quenched by adding 4 ml. [O]of 0.10 N hydr[d]ochloric acid (HCl) and the absorbance is read at 340nm. A 1.5mM L-leucine solution is used as the standard. Transformation of the measured leucine amino equivalents to a degree of hydrolysis is carried out by means of a standard curve for each particular protein substrate (Adler Nissen, J. (1979) J. Agri. Food Chem. 27,6, 1256-1262).

The paragraph beginning on line 1 of page 10 is amended as follows:

Example 2

300g of defatted soy flour is dispersed in 1500 ml of water and the pH of the dispersion was adjusted to 5.5[.] using 1N HCl. The solution was stirred with mechanical stirrer and the temperature raised to 55°C. 1.5g of papain was added and stirring continued for 3 h. The enzyme was inactivated by boiling for 5 min. The pH of the hydrolysate was adjusted to 6.8 using 6N NaOH. The slurry was cooled and centrifuged. The clear solution was spray dried. The yield was 21% (on flour basis) and degree of hydrolysis was 30%.

The paragraph beginning on line 10 of page 10 is amended as follows:

Example 3

1 kg g of defatted soy flour was dispersed in 5000 ml of water and the pH of the dispersion was adjusted to 5.0[.] using 1N HCl. The solution stirred with mechanical

stirrer and then the temperature raised to 50°C. 5 g of papain was added and stirring continued for 4 hrs. The enzyme was inactivated by boiling for 5 min. The pH of the hydrolysate as adjusted to 6.5 using 6N NaOH. The slurry was cooled and centrifuged. The clear solution was spray dried. The yield was 20% (on flour basis) and degree of [H]hydrolysis was 30%.

The paragraph beginning on line 27 of page 10 is amended as follows:

The soy protein hydrolysate obtained has 25-30 trypsin inhibitor Unit/mg (TIU/mg) activity, 95-98% nitrogen solubility index, 1.0-1.4% of salt content (measured as C1 ions) and 2 – 2.2 g/100 ml bitterness recognition threshold units. The lipoxygenase and urease activities were not detectable. The amino acid composition of the soy protein hydrolysate obtain was similar to the amino acid make up of starting raw material thereby retaining the nutritional value. The protein hydrolysate is less bitter compared to protein hydrolysate obtained from casein and is less hygroscopic in nature.

IN THE CLAIMS

Claim 1 is amended as follows:

1. (Amended) A process for the preparation of a protein hydrolysate from soy flour, said process comprising: (1) hydrolyzing an aqueous slurry of defatted soy flour containing from 6-30% solid content w/v using a proteolytic enzyme of plant origin at pH 5-9 and temperature of 53 ± 5°C under stirring for a range of from 30 minutes to 6 hours; (2) inactivating the enzyme [by a known [matter]manner; (3)[neutralizing] adjusting the pH value of the slurry to a range between about 6 and about 7; and (4) separating [the]solids by a known manner and drying the resultant clarified liquor [so obtained]to [get the]obtain said hydrolysate.

Claim 3 is amended as follows:

3. (Amended) A process as claimed in claim 1, wherein the plant origin proteolytic enzyme is selected from the group [comprising]consisting of papain and bromelin.

Claim 4 is amended as follows:

4. (Amended) A process as claimed in claim 1, wherein 0.4-0.6% w/w[/]of the proteolytic enzyme is added to the soy flour.

Claim 5 is amended as follows:

5. (Amended) A process as claimed in claim 1, wherein the hydrolysis is effected for a period of 3-4 hours.

Claim 6 is amended as follows:

6. (Amended) A process as claimed in claim 1, wherein the drying is effected by freeze drying, spray drying, [and]or drum drying.

Delete claim 7 and 8.

Claim 9 is amended as follows:

9. (Amended) A process as claimed in claim 1, wherein the protein hydrolysate has 2-2.2g/100ml bitterness recognition threshold units.

Delete claim 1.

Claim 11 is amended as follows:

11. (Amended) A process as claimed in claim 1, wherein [high yield of]the protein hydrolysate obtained in step (4) has [with] 30 to 35% degree of hydrolysis, [is

obtained from the raw material taken] as determined by Trinitrobenzenesulphonic acid (TNBS) procedure.

Claim 12 is amended as follows:

12. (Amended) A process as claimed in claim 1, wherein the protein hydrolysate obtained has a [creamy]color of cream and a yield of 20-25% [(]on flour basis[)].

Claim 13 is amended as follows:

13. (Amended) A process as claimed in 1, wherein protein hydrolysate has 3.0 to 5.0% moisture, 8.0 to 8.5% nitrogen, and 30.0-35.0% degree of hydrolysis, as determined by Trinitrobenzenesulphonic acid (TNBS) procedure.

Claims 16, 17, 18, and 19 are cancelled.

Claim 20 is amended as follows:

20. (Amended) A protein hydrolysate obtained from soy flour, comprising [lour]from 20 to 30 trypsin inhibitor units/mg activity, 95 to 98% Nitrogen Solubility Index, 1 to 1.4% of salt content, 3 to 5% moisture, 8 to 8.5% nitrogen and 30 to 35% degree of hydrolysis, as determined by Trinitrobenzenesulphonic acid (TNBS) procedure.

Claim 22 is amended as follows:

22. (Amended) A protein hydrolysate as claimed in claim 20, [further] comprising 2 to 2.2g/100 ml bitterness recognition threshold units.

Claims 23, 24, 25, and 26 are cancelled.

Claim 27 is amended as follows:

27. (Amended) A protein hydrolysate as claimed in claim 20, [has cream color]which is the color of cream.

Claims 28 and 29 are new.

28. (New) A process as claimed in claim 1, wherein the protein hydrolysate obtained in Step (4) is soluble in water at a range of pH from 1 to 14.

29. (New) A protein hydrolysate as claimed in claim 20, which is soluble in water at a range of pH from 1 to 14.